

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NATIONAL STARCH AND CHEMICAL  
INVESTMENT HOLDING  
CORPORATION, PENFORD  
AUSTRALIA LTD., and PENFORD  
HOLDINGS PTY,

Plaintiffs,

v.

CARGILL, INC. and  
MGP INGREDIENTS, INC.,

Defendants.

C.A. No. 04-1443-GMS

**DEFENDANTS' OPENING MARKMAN BRIEF**

**FISH & RICHARDSON P.C.**

Thomas L. Halkowski (#4099)  
919 N. Market Street, Suite 1100  
P.O. Box 1114  
Wilmington, DE 19899-1114  
Telephone: (302) 652-5070  
Facsimile: (302) 652-0607

*Attorney for Defendants  
Cargill, Inc. and MGP Ingredients, Inc.*

Filed: September 26, 2005

## TABLE OF CONTENTS

	<u>Page</u>
I. NATURE AND STAGE OF THE PROCEEDING.....	1
II. SUMMARY OF ARGUMENT .....	1
III. CONCISE STATEMENT OF FACTS .....	2
A. The Development of “High” Amylose Corn .....	2
B. Measuring the “Apparent” Amylose Content.....	4
C. The Claim Language and Specification of the Patents in Suit .....	6
D. The Prosecution History of the Patents in Suit .....	7
IV. ARGUMENT .....	10
A. The Applicable Legal Standards .....	10
B. The Intrinsic Record Shows that “Apparent Amylose Content” in the ’840 Patent Includes Amylose Content as Measured by at Least Any Colorimetric Iodine Analysis.....	11
1. The Claim Language and Specification Both Indicate that “Apparent Amylose Content” Can Be Measured by More than One Method.....	11
2. The Prosecution History Establishes That “Apparent Amylose Content” Includes Amylose Content as Measured by at Least Any Colorimetric Iodine Analysis.....	12
3. Nothing in the Intrinsic Record Limits “Apparent Amylose Content” to Only One of the Two Exemplary Colorimetric Test Methods Disclosed in the Specification. ....	14
C. “Amylose Content” in the ’454 Patent Similarly Includes Amylose Content as Measured by Any Colorimetric Iodine Analysis.....	16
V. CONCLUSION.....	17

**TABLE OF AUTHORITIES**

	<u>Page(s)</u>
<b><u>Cases</u></b>	
<i>Engel Indus., Inc. v. Lockformer Co.</i> , 96 F.3d 1398 (Fed. Cir. 1996).....	11
<i>Genentech, Inc. v. Wellcome Found. Ltd.</i> , 29 F.3d 1555 (Fed. Cir. 1994).....	13
<i>Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.</i> , 381 F.3d 1111 (Fed. Cir. 2004).....	10
<i>Lemelson v. Gen. Mills, Inc.</i> , 968 F.2d 1202 (Fed. Cir. 1992).....	13
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005).....	10, 14
<i>Southwall Techs., Inc. v. Cardinal IG Co.</i> , 54 F.3d 1570 (Fed. Cir. 1995).....	15
<i>Vitronics Corp. v. Conceptronic, Inc.</i> , 90 F.3d 1576 (Fed. Cir. 1996).....	11
<i>Vivid Techs., Inc. v. Am. Science &amp; Eng'g, Inc.</i> , 200 F.3d 795 (Fed. Cir. 1999).....	10

## **I. NATURE AND STAGE OF THE PROCEEDING**

Plaintiffs National Starch and Chemical Investment Holding Corp., Penford Australia Ltd., and Penford Holdings Pty sued Defendants Cargill, Inc. and MPG Ingredients, Inc. for infringement of U.S. Patent Nos. 5,977,454 (the “‘454 patent”) and 6,409,840 (the “‘840 patent”). The ’454 and ’840 patents are entitled “High Amylose Starch and Resistant Starch Fractions,” and specifically relate to corn starch. The ’454 patent generally claims corn seed containing a recessive amylose extender gene and having an “amylose content” of greater than 80% or more by weight. The ’840 patent claims corn starch having an “apparent amylose content” greater than 90.1%. With this *Markman* brief, Defendants ask the Court to define the claim limitations “amylose content” and “apparent amylose content” synonymously—to include amylose content as measured by at least any colorimetric iodine analysis.

## **II. SUMMARY OF ARGUMENT**

1. The Court should construe the “apparent amylose content” limitation in the ’840 patent to include amylose content as measured by at least any colorimetric iodine analysis based on the intrinsic evidence. The term “apparent amylose content” was commonly understood in the prior art to include amylose content as measured by a variety of methods, and both the claim language and specification are consistent with this understanding. Moreover, events during the prosecution history dictate that the term include amylose content as measured by at least any colorimetric iodine analysis to avoid a large body of prior art that the applicants conceded would otherwise anticipate the claims.
2. The Court should construe “amylose content” as used in the ’454 patent synonymously with “apparent amylose content” in the ’840 patent based on the examiner’s unchallenged statement during prosecution that “apparent amylose content” in the ’840 patent means the same thing as “amylose content” in the common parent application to both the ’840 and ’454 patents.

### III. CONCISE STATEMENT OF FACTS

Nearly all of the starch made and used in the United States comes from corn, primarily normal dent corn. [Declaration of Courtney Nelson Wills in Support of Defendants' Opening *Markman* Brief (hereinafter "Nelson Wills Decl.") Ex. 5 at A92 (Virgil Fergason, "High Amylose and Waxy Corns" in *Specialty Corn* p. 56 (1994)).] Corn starch finds uses not only in the food industry, but also in the chemical industry as a major component of fibers, adhesives, plastic films, and molded articles. [Nelson Wills Decl. Ex. 6 at A114-A125 (Roy Whistler, "History and Future Expectation of Starch Use," in *Starch, Chemistry and Technology*, 2nd Ed. (1984); Ex. 7 at A126 (Wolff et al., "The Structure of a New Starch of High Amylose Content," *J. Chem. Soc.*, 77:1654-59 (1955)).] These wide-ranging uses stem from starch's two carbohydrate components—amylose, a linear polymer of glucose, and amylopectin, a branched polymer of glucose—that provide unique and useful physical and chemical properties to the products made with starch. What is meant by, and how to measure, the amylose content of corn starch in the prior art and the patents in suit follows.

#### A. The Development of "High" Amylose Corn

The relative amount of amylose to amylopectin in starch affects the properties of the products made from it. For normal dent corn, amylose makes up about 25% of the total starch content by weight. [Nelson Wills Decl. Ex. 5 at A92 (Virgil Fergason, "High Amylose and Waxy Corns" in *Specialty Corn* p. 56 (1994)).] While starch separation and fractionation methods provided techniques to obtain starch with varying percentages of amylose and amylopectin, the real opportunity for the corn starch market immediately following World War II was to use corn lines that naturally produce starches with varying percentages of amylose and amylopectin.

Conveniently, corn mutants that produce starch with altered amounts of amylose relative to amylopectin have existed for well over fifty years. The first mutant, one that existed before World War II, had no amylose and was called “waxy” corn because of its visual appearance. [Nelson Wills Decl. Ex. 6 at A122-A123 (Roy Whistler, “History and Future Expectation of Starch Use,” in Starch, Chemistry and Technology pp. 6-7 (2nd ed. 1984).] The next mutant, identified shortly after the war, was the amylose extender (“ae”) mutant. [Nelson Wills Decl. Ex. 6 at A123 (Roy Whistler, “History and Future Expectation of Starch Use,” in Starch, Chemistry and Technology p. 7 (2nd ed. 1984)); Ex. 8 at A132-136 (Robert Bear, “The Story of Amylomaize Hybrids, Chemurgic Digest, 17(5):5-7 (1958).] The ae mutant was the antithesis of waxy; it increased amylose content. These corn mutants were called “amylomaize.” The first amylomaize contained roughly an equal distribution of amylose and amylopectin. [*Id.*] First-generation amylomaize hybrids—class V amylomaize having 50% amylose—were grown in 1958. [*Id.*] Continued development of the ae mutant resulted in corn hybrids producing starch with anywhere from 60 to 85% amylose. [Nelson Wills Decl. Ex. 6 at A123 (Roy Whistler, “History and Future Expectation of Starch Use,” in Starch, Chemistry and Technology, p. 7 (2nd ed. 1984); Ex. 7 at A126-A131 (Wolff et al., “The Structure of a New Starch of High Amylose Content,” J. Chem. Soc., 77:1654-59 (1955)); Ex. 9 at A141 (Senti, “High-Amylose Corn Starch: Its Production, Properties, and Uses” in Starch: Chemistry and Technology p. 501 (1967)).] Class VII amylomaize (typically 70-80% amylose) became available in 1963, the same year class VIII (minimum of 80% amylose) was grown experimentally. [Nelson Wills Decl. Ex. 9 at

A141-A142 (Senti, “High-Amylose Corn Starch: Its Production, Properties, and Uses” in Starch: Chemistry and Technology p. 501-02 (1967)).]

#### **B. Measuring the “Apparent” Amylose Content**

When a measured “amylose content” is reported in the high amylose corn starch art, this almost always refers to the “apparent amylose content” of the corn starch. The phrase “apparent amylose content” is used to reflect the discrepancy that sometimes exists between the amylose content measured using available analytical methods and what would be the “true” amylose content in that same starch sample if not for limitations in the analytical methods. The most common analytical methods used to measure amylose content in the art—which include both potentiometric and colorimetric methods—measure the “apparent amylose content.” [Nelson Wills Decl. Ex. 5 at A94 (Virgil Fergason, “High Amylose and Waxy Corns,” in Specialty Corns p. 58 (1994)).] In potentiometric methods, the starch sample is often titrated using iodine to determine the relative amylose content. [*Id.*] In colorimetric methods, the starch sample is mixed with a reagent that reacts to or complexes with the amylose to form a distinctive color, and the absorbance or intensity of that color is measured with a spectrophotometer. [*Id.*] When the reagent in the colorimetric method is iodine, which complexes with amylose to form a brilliant blue color, this is commonly referred to as a “blue value” colorimetric test. [Nelson Wills Decl. Ex. 10 at A176 (Thomas Schoch, “[40] Iodimetric Determination of Amylose Iodine Sorption: ‘Blue Value’,” Methods in Carbohydrate Chemistry, Vol. IV, at 168 (1964); Ex. 7 at A127 (Wolff et al., “The Structure of a New Starch of High Amylose Content,” J. Chem. Soc., 77:1654-59 at 1655 (1955)).]

Many variations on both the potentiometric and colorimetric, including blue value, methods exist in the high amylose corn starch art. [Nelson Wills Decl. Ex. 11 at

A189-A192 ("Amylose (Blue Value)," International Standard Analytical Methods of Member Companies of the Corn Industries Research Foundation, a Division of the Corn Refiners Association, Inc., Tentative Standard 7-25-75); Ex. 12 at A193-A203 (Wolf et al., "Amylose Determination in Dimethyl Sulfoxide Extracts of Maize," Cereal Chem. 47:1-6: 437-446 (1970)); Ex. 7 at A127 (Wolff et al., "The Structure of a New Starch of High Amylose Content," J. Chem. Soc., 77:1654-59 at 1655 (1955) (referring to the blue value procedures of McCready and Hassid); Ex. 13 at A204-A207 (C.A. Knutson, "A Simplified Colorimetric Procedure for Determination of Amylose in Maize Starches," Cereal Chem. 63(2):89-92 (1986)); Ex. 10 at A163-A188 (Methods in Carbohydrate Chemistry, Volume IV, Chapters 37-41 (1964)) (disclosing five different methods, including both potentiometric and colorimetric methods, to measure amylose content).]

All of these various methods, however, have long been understood to measure the "apparent amylose content" of the starch. [Nelson Wills Decl. Ex. 12 at A196 (Wolf et al., "Amylose Determination in Dimethyl Sulfoxide Extracts of Maize," Cereal Chem. 47:1-6: 437-446 at 439 (1970) (stating that "[a]mylose content of the starch was determined spectrophotometrically by measuring absorbance of the amylose-iodine complex" and noting in an accompanying footnote that "[t]he term 'amylose' as used here is equivalent to the term 'apparent amylose'")); Ex. 7 at A126-A131 (Wolff et al., "The Structure of a New Starch of High Amylose Content," J. Chem. Soc., 77:1654-59 at 1655 (1955) ("Determination of Blue Values ... The amylo maize starch had an apparent amylose content of 58%.")); Ex. 14 at A213 (Boyer et al., "Changes in Starch Granule Size and Amylose Percentage During Kernel Development in Several Zea Mays L. Genotypes," Cereal Chemistry, 53:3: 327-337 at 330 (1976) ("Apparent amylose

percentage of dimethyl sulfoxide dispersed starch samples were determined by the blue value method of Wolf et al.”).]

Virgil Fergason, a former research director at Plaintiff National Starch, explained the industry’s long-held understanding on apparent amylose content in connection with these various methods in a chapter he wrote for a book on specialty corn:

Various methods have been used to determine amylose-amylopectin ratios. Potentiometric iodine titrations and spectrophotometric analyses have been used extensively to determine amylose-amylopectin ratios of various starches. The latter method is based on the absorbency of the starch-iodine complex (also called blue-value procedure) and on relating the degree of absorbency to known amylose and amylopectin standards. The potentiometric method is based on the amount of iodine bound by 100 mg of starch and compared to the amount bound by a purified amylose standard. A review of these methods by Shannon and Garwood points out that the amylose estimated by these procedures should be considered “apparent amylose” because the occurrence of branched chain components with long external chains can result in an overestimation of amylose.

[Nelson Wills Decl. Ex. 5 at A94 (Virgil Fergason, “High Amylose and Waxy Corns,” in Specialty Corns p. 58 (1994)).] Thus, amylose content, when measured via a variety of potentiometric and colorimetric methods, means—and is understood to mean—the “apparent” amylose content.

### **C. The Claim Language and Specification of the Patents in Suit**

The patents in suit purport to announce an increase in the amylose content of corn and corn starch beyond levels already obtained in the prior art. They claim maize, a scientific name for corn, and maize starch having an “amylose content” and “apparent amylose content” above a certain level. The patents in suit use the terms “amylose content” and “apparent amylose content” consistent with the common understanding in the art—the terms are used synonymously and include amylose content as measured by more than one particular method.

Consistent with the common understanding in the art, the claims themselves do not identify any particular test methods that must be used to determine the “amylose content” or “apparent amylose content” of the starch. In addition, the common specification to both patents refers to at least two different colorimetric methods and one potentiometric method to measure the apparent amylose content of corn starch. One of the colorimetric methods is used to measure the amylose content of the corn hybrids disclosed in the patents. [Nelson Wills Decl. Ex. 2 at A17 ('840 patent, col. 3, lines 4-6); Ex. 1 at A7 ('454 patent, col. 3, lines 6-8).] The second colorimetric method and the potentiometric method are as described in the Cluskey et al. reference cited in the specification. [Nelson Wills Decl. Ex. 2 at A16 ('840 patent, col. 2, lines 16-22), Ex. 1 at A6 ('454 patent, col. 2, lines 18-24); Ex. 15 at A221-A226 (Cluskey et al., in Starch, 32:105-09 (1980)).] Nowhere in the common specification, however, does it state that the claims should be exclusively limited to any of these methods.

Finally, the common specification uses “amylose content” and “apparent amylose content” interchangeably. [Nelson Wills Decl. Ex. 2 at A20 ('840 patent, claims 1-5); Ex. 1 at A10 ('454 patent, claims 1-13). When describing and reporting the amylose concentration of the corn hybrids disclosed in the patents, the patents refer to the “amylose content” of the hybrids even though the patents make clear the method used to determine the amylose content was the “apparent amylose content” method at column 3 of the patents. [Nelson Wills Decl. Ex. 2 at A18 ('840 patent, col. 5, lines 10-14); Ex. 1 at A8 ('454 patent, col. 5, lines 10-14).] And when discussing the “correlation between amylose content and size fraction” the patents report an “apparent amylose content.” [Nelson Wills Decl. Ex. 2 at A16, A19 ('840 patent, col. 2, lines 24-34 and col. 8, lines 27-30); Ex. 1 at A6, A9 ('454 patent, col. 2, lines 25-35 and col. 8, lines 13-15).]

#### **D. The Prosecution History of the Patents in Suit**

The prosecution histories of the patents in suit also establish that the “apparent amylose content” and “amylose content” claim limitations are used interchangeably and

can be measured by more than one method. Both patents in suit are divisional applications claiming priority to parent application no. 08/374,645, which ultimately issued as U.S. Patent No. 5,714,600 (the “’600 patent”). [Nelson Wills Decl. Ex. 2 at A11 (’840 patent, cover page listing “Related U.S. Application Data”); Ex. 1 at A1 (’454 patent, cover page listing “Related U.S. Application Data”); and Ex. 3 at A21 (’600 patent, cover page identifying “Appl. No.” of the patent).] That is they both extend from a common parent: the ’600 patent.

During the prosecution of the ’840 patent—which now claims maize starch having an “apparent amylose content” above 90.1% or more—the original claims recited a maize starch having an “amylose content” of above 80% or more. [Nelson Wills Decl. Ex. 4 at A56-A57, A60-A61 (App’n No. 08/967,826, Paper No. 1 at p. 18-19 (originally pending claims 8-15) and Paper No. 3 at p. 1-3 (preliminary amendment to pending claims)).] The examiner rejected these original claims under 35 U.S.C. § 102(b) as being anticipated by a 1967 review article on “High-Amylose Corn Starch: Its Production, Properties, and Uses” by R.F. Senti and similar prior art. The examiner explained that the Senti article was “representative of the large body of prior art teaching starch having up to 85% apparent amylose.” [Nelson Wills Decl. Ex. 4 at A67 (App’n No. 08/967,826, Paper No. 9 at 2).] Moreover, the examiner described the relationship between this large body of prior art and the pending patent application as follows:

Much of the prior art relies on amylose determination based on iodine affinity such as colorimetric, as in the instant application, or potentiometric. The prior art measures this “apparent” amylose by iodine affinity also. Interpreting the claims in light of the specification, the instant claims must be read as “. . . maize starch having an amylose content of more than 80%, *as measured by colorimetric iodine analysis . . .*”. Senti teaches maize starch containing 85% amylose as measured by colorimetric iodine affinity analysis and gel compositions made therewith.

[Nelson Wills Decl. Ex. 4 at A67-68 (App’n No. 08/967,826, Paper No. 9 at 2-3).]

In response to this rejection, the applicants amended the claims adding “apparent” to “amylose content” and increasing “more than 80%” to “more than 90.1%.” [Nelson Wills Decl. Ex. 4 at A72-74 (App’n No. 08/967,826, Paper No. 10 at 1-3).] In addition to amending the claims, the applicants also argued the following to overcome the Senti article and the large body of similar prior art:

Broad claims . . . were rejected under 35 U.S.C. §102(b) as anticipated by the reference to Senti. The Examiner did not provide a copy of reference but indicated that it was representative of a large body of prior art teaching starch having up to 85% apparent amylose. In order to avoid this reference, Applicants have amended the main claims in this application to indicate that the minimum starch amylose content in the starch is 90.1% . . . . Therefore, it is believed that the enclosed amendments and above remarks are sufficient to place all claims in this application in condition for allowance.

[Nelson Wills Decl. Ex. 4 at A75-A76 (App’n No. 08/967,826, Paper No. 10 at 4-5).] Based on the above claim amendments and arguments, the examiner removed the § 102(b) rejection over Senti and the large body of similar prior art.

The examiner added, however, a double-patenting rejection under 35 U.S.C. § 101 in view of the ’600 patent—the original parent application. The examiner explained that because the terms “amylose content” as recited in the ’600 patent and “apparent amylose content” as recited in the application were “defined alike,” the applicants were again attempting to claim the same invention already claimed in claims 3, 4, 7, and 8 of the ’600 patent. [Nelson Wills Decl. Ex. 4 at A82 (App’n No. 08/967,826, Paper No. 13 at 2); Ex. 3 at A30 (’600 patent, claims 3, 4, 7, and 8).] Although the applicants overcame this rejection by noting that claims 1-8 of the ’600 patent had been cancelled, they did not attempt to refute the examiner’s assertion that “apparent amylose content” and “amylose content” meant the same thing in these related applications. [Nelson Wills Decl. Ex. 4 at A86-A87 (App’n No. 08/967,826, Paper No. 15 at 1-2).]

These events during prosecution establish that both “apparent amylose content” and “amylose content,” as used in the claims of the patents in suit, mean at least as measured by any colorimetric iodine analysis.

#### IV. ARGUMENT

##### A. The Applicable Legal Standards

To construe the two claim limitations in dispute, the Court must determine what “apparent amylose content” and “amylose content” would mean to one of ordinary skill in the art as of the effective filing date of the patents in suit. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). This determination is made primarily in view of the intrinsic evidence (i.e., the claim language as a whole, the other claims of the patents in suit, the specification, and the prosecution history) and secondarily in view of extrinsic evidence such as expert testimony, dictionaries, and technical publications. *See Phillips*, 415 F.3d at 1313. The Court is not required to follow any magic formula or particular sequence of steps to construe the claims as long as appropriate weight is given to each interpretive source and primary importance is placed on the intrinsic evidence. *See id.* at 1324.

As part of the intrinsic evidence, positions taken by the examiner and patentee during prosecution of the patents at issue often play an important role in claim construction. *See, e.g., Vivid Techs., Inc. v. Am. Science & Eng’g, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999) (“The prosecution history is often helpful in understanding the intended meaning as well as the scope of technical terms, and to establish whether any aspect thereof was restricted for purposes of patentability.”). This is especially true when the applicant distinguishes the claims over particular prior art. *Engel Indus., Inc. v.*

*Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996) (“Prosecution history is especially important when the invention involves a crowded art field, or when there is particular prior art that the applicant is trying to distinguish.”) (internal quotation omitted); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996) (noting that “the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims” and that “[i]ncluded within an analysis of the file history may be an examination of the prior art cited therein” that gives clues as to what the claims do not cover). In this case, the intrinsic record, including the prosecution history, firmly establishes the meaning of the disputed claim terms.

**B. The Intrinsic Record Shows that “Apparent Amylose Content” in the ’840 Patent Includes Amylose Content as Measured by at Least Any Colorimetric Iodine Analysis.**

**1. The Claim Language and Specification Both Indicate that “Apparent Amylose Content” Can Be Measured by More than One Method.**

As discussed above, both the claim language and specification use the term “apparent amylose content” consistent with the ordinary meaning as understood in the high amylose corn art—i.e., to include the amylose content as measured by a variety of analytical methods. The claims themselves merely specify “apparent amylose content” and do not identify any particular method by which this limitation must be measured. Similarly, the specification does not specifically define this term and, in fact, uses “apparent amylose content” in connection with at least two different methods, suggesting that it should not be limited to one particular method.

**2. The Prosecution History Establishes That “Apparent Amylose Content” Includes Amylose Content as Measured by at Least Any Colorimetric Iodine Analysis.**

As with the claim language and the specification, the prosecution history further reinforces that “apparent amylose content” includes amylose content as measured by more than one method. In particular, the term must include amylose content as measured by at least any colorimetric iodine analysis. During prosecution, the examiner rejected the claims over a large body of prior art disclosing an “apparent amylose content” of up to 85% as determined by a number of iodine affinity methods, including the various colorimetric and potentiometric methods known in the art. [Nelson Wills Decl. Ex. 4 at A67-A69 (App’n No. 08/967,826, Paper No. 9 at 2-4).] As an example of such prior art, the examiner pointed to the Senti article as disclosing corn starch containing 85% apparent amylose as measured by colorimetric iodine affinity. Because the examiner concluded that the pending claims “*must be*” read as similarly disclosing corn starch having an amylose content of more than 80%, “*as measured by colorimetric iodine analysis*,” these claims were anticipated by prior art such as Senti. [Nelson Wills Decl. Ex. 4 at A67-A69 (App’n No. 08/967,826, Paper No. 9 at 2-4).] In response, the applicants conceded that Senti was representative of a body of prior art disclosing corn starch having up to 85% apparent amylose content, including as measured by colorimetric methods. [Nelson Wills Decl. Ex. 4 at A75-A76 (App’n No. 08/967,826, Paper No. 10 at 4-5).] And to overcome this reference, the applicants amended the claims to recite an “apparent amylose content” of 90.1% or more, rather than merely an “amylose content” of 80% or more.

In the context of the examiner’s objection, the amended claims must mean amylose content as measured by at least any colorimetric iodine analysis for at least three

reasons. First, the examiner used the term “apparent” to generally include at least all colorimetric analyses in a large body of known prior art—including the two different methods disclosed in the patent application itself—and the applicants added this term to their claims without any attempt to define it in a different manner. Second, the examiner specifically stated that the pending claims “*must be*” read to mean apparent amylose content “*as measured by colorimetric iodine analysis*,” and rather than contesting this characterization of the claims, the applicants embraced this definition by adding the word “apparent” to modify “amylose content.” Third, the applicants conceded that the claims would otherwise be invalid over the Senti article and similar prior art but for the claim amendments.

The only way to ensure that the amended claims overcame this prior art, however, was to include within the ambit of the claims “apparent amylose content” as measured by at least any colorimetric iodine analysis method disclosed in Senti and similar prior art. *Cf. Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1562-63 (Fed. Cir. 1994) (holding that even though the claim was silent as to the test method used to determine the specific activity limitation, the prosecution history dictated that the limitation be measured using the same type of assay that was used in a particular prior art reference to distinguish the claims from that prior art reference). Because Senti represented a body of prior art disclosing an apparent amylose content of up to 85% as measured by various colorimetric iodine analyses known in the art, the claims would avoid this prior art only if they excluded from their boundaries starch having an amylose content of 85% or less as measured by any of these known colorimetric iodine analyses. *See Lemelson v. Gen. Mills, Inc.*, 968 F.2d 1202, 1206 (Fed. Cir. 1992) (adopting a particular construction

based on what was patentable over the prior art in the prosecution history and noting that the “[p]rosecution history is especially important when . . . there is particular prior art that the applicant is trying to distinguish”). Thus, to ensure that the claims avoided Senti and similar prior art, the applicants had to amend the claims to read only on starch having an “apparent amylose content” in excess of 90.1% as measured by at least any colorimetric iodine analysis.

**3. Nothing in the Intrinsic Record Limits “Apparent Amylose Content” to Only One of the Two Exemplary Colorimetric Test Methods Disclosed in the Specification.**

As a threshold matter, the claim language merely states “apparent amylose content” and not apparent amylose content as measured by any specific method disclosed in the specification. Contrary to Plaintiffs’ assertion in the Joint Preliminary Claim Construction Chart, the portion of the specification introducing this exemplary method also does not define “apparent amylose content” as used in the claims. [See D.I. 36 at p. 2.] When describing the method detailed in the specification, the specification merely states that “[f]or the purposes of the description of the invention, the method by which amylose was determined is set out below.” The specification gave the method a generic title: “METHOD: Apparent Amylose (Blue Value).” Although this method was purportedly used to describe the various embodiments of the invention, the specification does not state that this method is the only one contemplated by the claims. *See, e.g., Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. . . . In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as

being limited to that embodiment.”). Further, such an argument ignores the other colorimetric method set forth in the patent: Cluskey et al.

Similarly, the prosecution history merely defined the claim term as being measured by at least any colorimetric iodine analysis. Nothing about the exchange between the examiner and the applicants limited the meaning of this limitation to the specific method disclosed in the patent. The examiner merely stated that the apparent amylose content should mean as measured by at least any colorimetric iodine analysis, and the applicants acquiesced to this interpretation. The examiner made no reference to the “METHOD: Apparent Amylose (Blue Value)” in the specification in defining the claims. Similarly, in overcoming the examiner’s rejection over Senti, the applicants amended the claims to state “apparent amylose content.” The applicants did not amend the claims to specify apparent amylose content as measured by the exemplary method in the claims.

Moreover, to the extent that the amylose content as measured by the specific method of the patent differs from the amylose content as measured by the colorimetric iodine analysis methods in the prior art, it would be improper to now allow Plaintiffs to exploit this difference to their advantage with regard to either infringement or validity.

*See, e.g., Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995)* (“A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a ‘nose of wax.’”). For example, if a given sample was tested as having 91% apparent amylose content by the specific method disclosed in the patent, but only 85% apparent amylose content by one of the colorimetric

iodine analysis methods of the prior art, the Plaintiffs cannot argue that this is conclusive proof of infringement of claims specifying an “apparent amylose content or more than 90.1%” especially since the 85% value falls within the range of admitted prior art. Similarly, the Plaintiffs should not now be able to argue that prior art disclosing greater than 90.1% apparent amylose content as measured by a colorimetric iodine analysis does not anticipate simply because it was not measured using the specific method disclosed in the patent. Because Plaintiffs admitted during prosecution that references such as Senti that disclose sufficiently high apparent amylose values based on colorimetric iodine analysis were anticipatory of the claims including such amylose values within their scope, they cannot assert that such references are non-anticipatory in litigation.

**C. “Amylose Content” in the ’454 Patent Similarly Includes Amylose Content as Measured by Any Colorimetric Iodine Analysis.**

The prosecution history also reveals that the term “amylose content” as used in the ’454 patent should have the same meaning as the term “apparent amylose content” in the ’840 patent. During the prosecution of the ’840 patent, the examiner stated, and the applicants did not refute, that “apparent amylose content” in the ’840 patent has the same meaning as “amylose content” in the ’600 patent—i.e., amylose content as measured by colorimetric iodine analysis. Because the ’454 patent issued as a child to the ’600 patent and also uses the same “amylose content” claim language as found in the ’600 patent, it should similarly be construed to mean amylose content as measured by at least any colorimetric iodine analysis. Moreover, although Plaintiffs advocate a different construction for the terms “apparent amylose content” and “amylose content,” they agree that the two terms should be interpreted the same.

**V. CONCLUSION**

For the foregoing reasons, Defendants request that the Court construe the claim limitations “apparent amylose content” and “amylose content” synonymously to include the amylose content as measured by at least any colorimetric iodine analysis.

Dated: September 26, 2005

FISH & RICHARDSON P.C.

By: /s/ Thomas L. Halkowski

Thomas L. Halkowski (#4099)  
919 N. Market Street, Suite 1100  
P.O. Box 1114  
Wilmington, DE 19899-1114  
Telephone: (302) 652-5070  
Facsimile: (302) 652-0607

Attorneys for Defendants  
Cargill, Inc. and MGP Ingredients, Inc.

**CERTIFICATE OF SERVICE**

I hereby certify that on September 26, 2005, I electronically filed **DEFENDANTS' OPENING MARKMAN BRIEF** with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following.

Josy W. Ingersoll  
Young Conaway Stargatt & Taylor, LLP  
The Brandywine Building, 17th Floor  
1000 West Street  
P.O. Box 391  
Wilmington, DE 19899-0391

*Attorneys for Plaintiffs*  
*National Starch and Chemical*  
*Investment Holding Corporation,*  
*Penford Australia Ltd., and Penford*  
*Holding Pty*

A copy was also served via hand delivery to the aforementioned on this date.

I hereby certify that on September 26, 2005, I have mailed by United States Postal Service, the document(s) to the following non-registered participants:

Richard L. DeLucia  
Kenyon & Kenyon  
One Broadway  
New York, NY 10004

*Attorneys for Plaintiffs*  
*National Starch & Chemical Investment*  
*Holding Corporation, Penford Australia*  
*Ltd., and Penford Holding Pty*

*/s/ Thomas L. Halkowski*  
\_\_\_\_\_  
Thomas L. Halkowski (#4099)